

### **REMARKS/ARGUMENTS**

Claims 1-21, 23-42, and 44-69 are currently pending in this application. By this amendment, claims 1, 7, 12, 25, 28, and 33 are amended as set forth in detail below. No new matter is added by these amendments. Applicants reserve the right to pursue any canceled subject matter in a related, co-pending application.

#### **Claim Amendments**

Claims 1 and 25 have been amended to recite an aspect of the present invention with greater particularity by specifying induction of a "rectal mucosal" CTL response, as well as by specifying "contacting a rectal mucosal tissue" with the antigen composition. Support for these amendments is found in the application as filed at, *e.g.*, page 10, lines 30-35; and page 11, lines 10-15.

Claims 7, 12, 18, and 33 have been amended for clarity. Claims 7 and 28 have been amended to correct an obvious typographical error by substituting " $\alpha$ " for "a" in the phrase "tumor necrosis factor a (TNFa)." Accordingly, claims 7 and 28 now recite, *inter alia*, "tumor necrosis factor  $\alpha$  (TNF $\alpha$ ).\" For the sake of consistency and clarity, dependent claims 12 and 33, which recite substantially corresponding subject matter, have been amended to insert " $\alpha$  (TNF  $\alpha$ )" following the term "tumor necrosis factor."

#### **Response to Restriction Requirement**

In response to the Restriction Requirement, Applicants elect, with traverse, to prosecute the claims of Group VIII, claims 1-16, 21, 23, 25-27, 42, and 44, drawn to a method of using HIV-1 antigen SEQ ID NO:9. Applicants reserve the right to file divisional or related applications to the claims of non-elected groups.

With respect to Applicants' traversal, Applicants first note that the present application is a divisional of a U.S. national phase of International Application No.

PCT/US98/19028. As such, any restriction of the present claims must be determined according to the unity of invention standard under the PCT Rules. The unity of invention standard, however, was not applied in the present case. Instead, the Examiner has applied the standards of distinctness and serious burden, which are inapplicable to the present application. For at least this reason, the present restriction requirement is improper.

To the extent that the Examiner may choose to maintain the present restriction based on the unity of invention standard, Applicants respectfully submit that such a decision should not be made final, since Applicants have not yet had the opportunity to address specific remarks of the Examiner under the proper standard for restriction in this case.

In any event, in the interest of compact prosecution of this case, Applicants note that, under PCT Rule 13.2, the requirement for unity of invention among a group of inventions is fulfilled where the inventions share at least one special technical feature, *i.e.*, a technical feature defining "a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." MPEP § 1850 (citing PCT Rule 13.2). In this case, all claims of all Groups relate to induction of a protective rectal mucosal CTL response via contacting a rectal mucosal tissue with antigen. At present, there is no evidence of record showing that this technical feature is not novel and inventive over the prior art.

Furthermore, according to MPEP § 1850(II), unity of invention is "to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims." This section further states that if "the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity of invention arises in respect of any claims that depend on the independent claims." It is also stated that no problem arises in the case of a genus/species situation where the genus claim avoids the prior art, provided the genus claim is directed only to alternatives of a similar nature and the species falls entirely within the genus. In the present case, it is clear that each of Groups I to XVII relate to particular antigens or classes of antigens that can be used in accordance with the generic method of independent claim 1, which, as indicated above, forms a single general inventive concept, particularly in the absence of any cited art to the contrary. As to Group

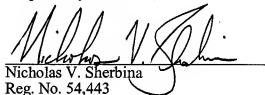
XVIII, because these claims recite an immunogenic composition for inducing a protective mucosal immune response and adapted for intrarectal administration, these claims also fall within a single general inventive concept together with the method claims of Groups I to XVII.

For at least the reasons above, Applicants respectfully request withdrawal of the present restriction requirement.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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